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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/701,698 | 11/05/2003 | Ricardo Blank | N-32769A | 7089 |

1095 7590 02/21/2007
NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

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| EXAMINER |
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BOGART, MICHAEL G

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| ART UNIT | PAPER NUMBER |
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3761

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 02/21/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/701,698

Applicant(s)

BLANK ET AL.

Examiner

Michael G. Bogart

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7, 8 and 10-23 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 7, 8 and 10-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claim 21 is objected to because of the following informalities: Claim 21 depends from claim 21. Appropriate correction is required. For the purposes of examination against the prior art, claim 21 is herein interpreted as depending from claim 20.

Claim 20 is objected to because of the following informalities: At the end of line 7, after “the”, there appears to be language missing.

Appropriate correction is required.

Claim Interpretation & 35 USC § 112 Paragraph 6

The claims as presently amended include means followed by a function.

A claim limitation will be presumed to invoke 35 U.S.C. § 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase “means for ” or “step for; ”
- (B) the “means for ” or “step for ” must be modified by functional language; and
- C) the phrase “means for ” or “step for ” must not be modified by sufficient structure, material, or acts for achieving the specified function.

With respect to the third prong of this analysis, see *Seal-Flex*, 172 F.3d at 849, 50 USPQ2d at 1234 (Radar, J., concurring) (“Even when a claim element uses language that generally falls under the step-plus-function format, however, 112 ¶ 6 still does not apply when the claim limitation itself recites sufficient acts for performing the specified function.”); *Envirco*

Art Unit: 3761

Corp. v. Clestra Cleanroom, Inc., 209 F.3d 1360, 54 USPQ2d 1449 (Fed. Cir. 2000). Thus, if the phrase “means for” or “step for” is modified by sufficient structure, material or acts for achieving the specified function, the USPTO will not apply 35 U.S.C. § 112, sixth paragraph, until such modifying language is deleted from the claim limitation. MPEP § 2181. In the instant case in claims 2 and 7, the means adapted to fit the enteral acquisition set is described subsequently in the claim as having a rigid tube part containing part of a passageway. Claim 2 also claims means adapted to fit the laminated paper packaging system is described subsequently in the claim as having a internally threaded portion. Claim 7 further has a means adapted to fit the laminated paper packaging system is described subsequently in the claim as having a spike. Claims 7 and 8 further describes attachment means for fixedly attaching the connector device to the packaging system described later in the claim as one or two rims with an upper surface and an adhesive layer. In claim 11, the venting means is described as a valve means. In claim 20, the first means is later described defining a second part of the passageway and further including second threaded portion.

Because of the specific structure in the claims defining the means, 35 USC § 112 paragraph six does not apply to the above examples.

Claims 11 and 16 do not meet the first and second prongs of the above analysis.

35 USC § 112 paragraph six does apply to the following limitations:

In claim 2, line 15, the means for opening the laminated paper packaging system.

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 12 combines the threaded attachment means of the embodiment of figures 1-3 and in the specification at page 10, line 10-page 15, line 22, with the visualization means of the embodiment shown in figure 6, and in the specification at page 17, line 21-page 18, line 4. There is no teaching in the specification or drawings that these features are combined in a single embodiment.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 3761

Claims 2, 3, 7, 8, 13, and 17-19 are rejected under 35 U.S.C. § 102(a) as being anticipated by Kawaguchi *et al.* (CA 2 432 623 A1; hereinafter "Kawaguchi").

Regarding claim 2, Kawaguchi teaches a connector device (12) capable of use with and enteral administration set (30) having a feeding line (30), and a laminated paper packaging system (20) comprising:

means (12d) capable of fitting to an enteral administration set (30), including a connector (112) which comprises a rigid tube part (112) capable of attachment of a feeding line (30) of an enteral administration set (30), the tube part (112) containing part of the passageway (12g) for the composition to be administered,

means (12a) capable of fitting to the laminated paper packaging system (20), wherein the means (112a) capable of fitting to the laminated paper packaging system (20) comprises an internally threaded portion (112b, 112s) capable of being screwed onto a corresponding outwardly threaded portion (114s) of a frame-like member (114) of the laminated paper package system (20),

a passageway (12g) capable of allowing the flow of a composition contained in the laminated paper packaging system (20) from the laminated paper packaging system to the enteral administration set (30) through the connector device (12),

and wherein the connector device further comprises means (112a) for opening of the laminated paper packaging system (20) upon screwing the connector device (112) onto the frame-like member of the laminated paper packaging system (20)(page 11, lines 9-12)(see figures 1 & 6, *infra*).

FIG. 1

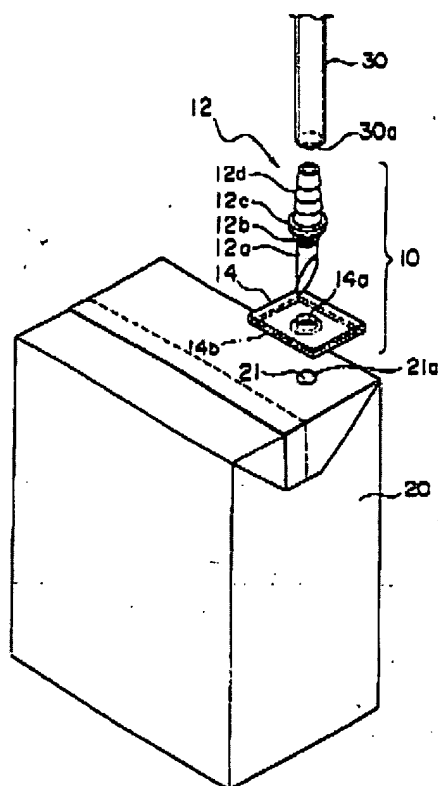
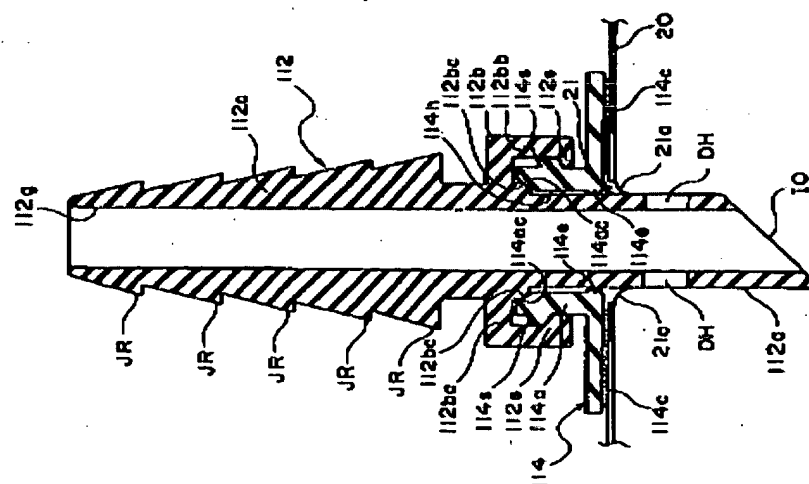


FIG. 6



Regarding the functional limitation of the claims, apparatus claims must be structurally distinguishable over the prior art. MPEP § 2114.

Regarding claim 3, Kawaguchi teaches that the means for opening the laminated paper packaging system comprises a cutting member (12a, 112a) protruding downwards from the connector device (12, 112) towards the laminated paper packaging system (20) for cutting the laminated paper packaging system (20) when the connector (12, 112) is screwed onto the frame-like member (114)(abstract).

Regarding claim 7, Kawaguchi teaches a means (12) capable of fitting to a laminated paper packaging system (20) includes a spike (112a) capable of penetrating into the interior of the packaging system (20) as well an attachment means (112s) capable of fixedly attaching the connector device (12) to the packaging system, the spike (112a) comprising the part of the passageway (112g) which is contained in the tube part (112) into the interior of the packaging system (20), and

a passageway (12g) capable of allowing the flow of a composition contained in the laminated paper packaging system (20) from the laminated paper packaging system to the enteral administration set (30) through the connector device (12),

wherein the attachment means (14) for fixedly attaching the connector device (12) to the laminated paper packaging system (20) comprises a rim (112b) having an upper surface facing towards the laminated paper packaging system, an adhesive layer (14b) being provided on the upper surface for attaching the connector (12) to the laminated paper packaging system (20) upon penetration of the spike (12a) and pressing of the upper surface of the rim (112b) with the adhesive layer (14b) against the laminated paper packaging system (20)(see fig. 6, supra).

Art Unit: 3761

Regarding claim 8, Kawaguchi teaches that the attachment means for fixedly attaching the connector device (12) to the laminated paper packaging system (20) comprises two rims (112b, 112s) extending in parallel around the spike (14a) axially spaced from each other at a predetermined distance, that rim (112b) located nearer to the point of the spike (12a) being made from a flexible material while that rim (12c) located farther from the point of the spike (14a) being made from a rigid material.

Regarding claim 13, Kawaguchi teaches a prefabricated enteral administration system comprising an enteral administration set (30) and a connector device (12) non-releasably connected to the enteral administration set (30).

Regarding claims 17 and 18, Kawaguchi teaches a kit comprising prefabricated enteral administration system (30) according and a laminated paper packaging system (20) containing a composition capable of being enterally administered to a patient.

Regarding claim 19, the Kawaguchi's connector (12) requires significant force to remove from the enteral administration set (30) is interpreted herein as being relatively non-releasable compared to a connector that lacks barbs (JR)(fig. 6).

Claims 2, 3, 7, 8, 13 and 17-19 are rejected under 35 U.S.C. § 102(e) as being anticipated by Kawaguchi *et al.* (US 2004/0104246 A1; hereinafter "'246").

'246 is the U.S. equivalent of Kawaguchi. All of the 102 rejections under Kawaguchi apply in the same manner under '246.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 14 and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawaguchi as applied to claims 2, 3, 7, 8, 13 and 17-19 above, and further in view of Quinn *et al.* (US 4,895,275) and Schafer (US 5,993,422 A).

Kawaguchi does not teach a pump unit or means of controlling administration of fluid to a user of that device.

Quinn teaches the use of a TETRA BRIK type container as an enteral feeding device.

Schafer teaches a device for dosing medical fluids which includes a pump (2)(abstract).

At the time of the invention, it would have been obvious to modify the fluid container of Kawaguchi so that it functions as a enteral device as taught by Quinn, and to further add the dosing means and pump of Schafer in order to provide automation of the complete system.

Art Unit: 3761

Claims 15 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawaguchi as applied to claims 2, 3, 7, 8, 13 and 17-19 above, and further in view of Quinn and Hindricks (US 3,001,525).

Kawaguchi does not teach an intermediate bag.

Quinn teaches the use of a TETRA BRIK type container as an enteral feeding device.

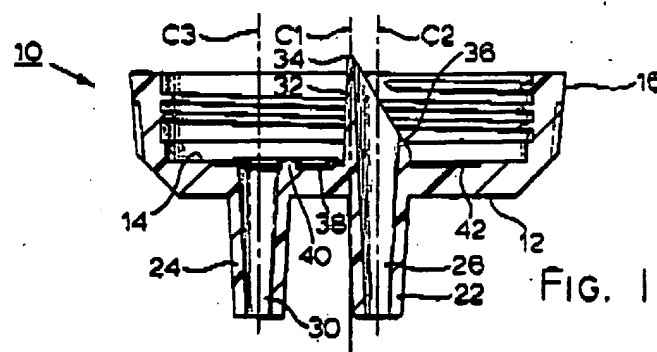
Hendricks teaches parenteral equipment that includes an intermediate bag (1) for mixing solutions.

At the time of the invention, it would have been obvious to modify the fluid container of Kawaguchi so that it functions as a enteral device as taught by Quinn, and to further add the intermediate bag of Hendricks in order to provide a means of reconstituting solutions.

Claims 10 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawaguchi as applied to claims 2, 3, 7, 8, 13 and 17-19 above, and further in view of Dickerhoff *et al.* (US 4,997,429).

Kawaguchi does not teach a vent or valve.

Dickerhoff teaches an enteral bottle cap (10) with a vent valve (24, 38) that permits entry of filtered air into the container while prevention liquid from exiting the container (see figure 1, *infra*). This provides for unimpeded flow of liquid through outlet (26).



Art Unit: 3761

At the time of the invention, it would have been obvious for one of ordinary skill in the art to add the vent valve of Dickerhoff to the connector of Kawaguchi in order to provide a means of venting the container while hooked up to a patient line.

Claims 20-23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawaguchi in view of Knierbein (US 6,485,479 B1).

Regarding claim 20, Kawaguchi teaches a connector device (112) capable of connecting an end of a feeding line (30) of an enteral administration set (30) to a laminated paper packaging system (20) containing a composition capable of being administered through the set (30), wherein the packaging system (20) includes a surface and a tubular frame-like member projecting (114) from the surface, the frame-like member (114) defining a first threaded portion (114s), the connector device (112) comprising:

a rigid tube part (112c) capable of sealingly engaging the end of the feeding line (30), the tube part (112c) defining a first part (112c) of a passageway (112g) for the composition,

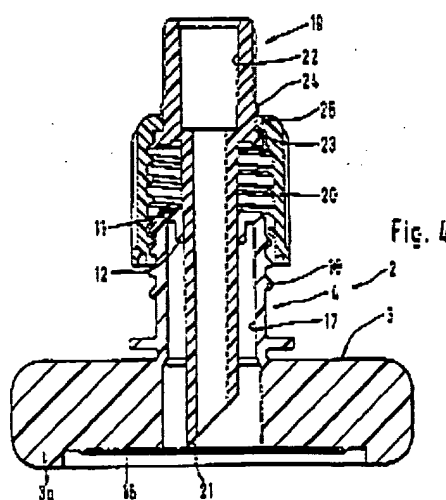
first means (112b) adapted to fit and attach the connector device (112) to the laminated paper packaging system (20), wherein the first means (112b) defines a second part (112b) of the passageway capable of allowing the composition to flow through the connector device (112) from the packaging system (20) into the feeding line (30), and wherein the first means (112b) includes a second threaded portion (112s) defined on the connector device (112), the second threaded portion (112s) being complementary to the first threaded portion (114s) of the frame-like member (114) of the laminated paper packaging system (20) such that the connector device (112) threadably engages the frame-like member (114) of the laminated paper packaging system (20); and

Art Unit: 3761

a cutting member (112a).

Kawaguchi does not teach a cutting member rotatable with the connector device upon screwing the connector device onto the frame-like member of the packaging system, the cutting member projecting toward the surface such that the cutting member is capable of first cutting the surface only after engagement of the second threaded portion of the connector device with the first threaded portion of the packaging system.

Knierbein teaches a cutting member (21) rotatable with the connector device (20) upon screwing the connector device (20) onto the frame-like member (4), the cutting member (21) projecting toward the surface such that the cutting member (21) is capable of first cutting a sealed (18) surface only after engagement of a second threaded portion of the connector device (20) with a first threaded portion (see fig. 4, *infra*). This offers the advantage that the connector can be pre-engaged to a container in a sterile manner and hooked up to a patient without rupturing the container. When it is time to start treatment, feeding, etc., a caregiver just needs to rotate the connector.



Art Unit: 3761

At the time of the invention, it would have been obvious to one of ordinary skill in the art to add the functional features of Knierbein's sterile connector to the laminated paper packaging system of Kawaguchi in order to provide a sterile means of hooking up a patient to the system prior to starting treatment.

Regarding claim 21, Knierbein teaches a cutting member (21) that is integral with the first means (20).

Regarding claim 22, Knierbein teaches a connector (20) that is non-releasably connected to a container (see col. 4, lines 30-35).

Regarding claim 23, Kawaguchi teaches a kit comprising prefabricated enteral administration system (30) according and a laminated paper packaging system (20) containing a composition capable of being enterally administered to a patient.

Response to Arguments

Applicant's arguments with respect to claims 10-12 and 20-23 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments regarding claims 2, 3, 7, 8 and 13-19, filed 29 November 2006 have been fully considered but they are not persuasive.

Regarding claims 2 and 7, applicants assert that many of their respective elements are in means-plus-function so as to invoke 35 – USC § 112 paragraph 6. This argument is not persuasive because all but one of these types of elements in the instant claims include sufficient structural limitations that they fail to satisfy the third prong of the test described in detail, supra.

Art Unit: 3761

Applicants assert that Kawaguchi fails to an internally threaded adapted to be fitted to the paper packaging system. This argument is not persuasive because as discussed supra, this is a function limitation. Apparatus claims must be structurally distinguishable over the prior art. The device of Kawaguchi can be rotated or screwed into place, even if it was not specifically designed to do that.

Applicants assert that Kawaguchi does not teach a rim or flange, but as described supra, elements (112b and 112s) are considered to be axially-spaced rims which face the packaging system (20).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3761

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart
19 February 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

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